IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: DIGITEK
PRODUCTS LIABILITY LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

PLAINTIFFS' MOTION TO COMPEL
DEPOSITION TESTIMONY

COME NOW Plaintiffs, and move this Court for an order compelling Actavis Defendants to answer deposition questions pertaining to the production, manufacturing processes, current good manufacturing practices, quality control, and quality assurance of all pharmaceuticals produced at the Actavis Totowa facilities during the relevant time period.

EXECUTIVE SUMMARY

Defendants have repeatedly entered objections and directed deponents not to respond to basic factual questions designed to elicit relevant and material information regarding manufacturing and quality department practices and procedures at the Actavis Totowa Facilities. In so doing, Defendants have misinterpreted and misapplied PTO 27 and PTO 37 to bar the orderly receipt of truthful and complete information. Plaintiffs have catalogued specific examples, which though not exhaustive, provide a record so this Court may see the misuse of these orders. Plaintiffs are entitled to inquire as to Defendants' Manufacturing and Quality Department practices and procedures, any violations of the current Good Manufacturing Practices ("cGMPs"), and the FDA inspections, all of which concern the rampant failure of

systems throughout the Actavis Totowa Facilities. Finally, this Honorable Court based its limitation on the scope of discovery on the sworn representations of Actavis employee Richard Dowling. As evidenced by his subsequent deposition testimony, Mr. Dowling's affidavit was false and misleading.

I. Testimony Elicited is Relevant and Reasonably Calculated to Lead to the Discovery of Admissible Evidence Because the Actavis Defendants Engaged in Uniform Practices and Procedures in their Manufacturing and Quality Departments with Digitek® and Other Drugs.

Pursuant to Federal Rule of Civil Procedure 37(a)(3)(B)(i), Plaintiffs seek an order compelling answers to questions propounded in this litigation under Fed. R. Civ. P. 30. Throughout the discovery process, and specifically in the depositions of Actavis' current and former employees, Defendants have used Pre-Trial Order 27 as an all-encompassing shield to the disclosure of any activity, practice, procedure, or protocol that could implicate other products manufactured by Actavis. Defense Counsel have repeatedly instructed witnesses not to answer questions, or to limit answers solely to Digitek®. The parties have conducted several meet and confer sessions[1] and extensive colloquy has been entered on the record regarding the interpretation of such objections. An example of Defendants' objections includes:

> Q. Did GMP issues ultimately result in the shutdown of production of all products in August 2008 at Actavis Totowa?
>
> MR. ANDERTON: Objection. You may answer. Actually, wait. I instruct you to answer only with respect to Digitek.
>
> THE WITNESS: With respect to Digitek, yes.

[1] The parties agreed that additional discussion would not solve this issue and mutually decided that this Court's intervention was necessary. As this motion involves prior court orders and numerous depositions, the parties choose to brief the issues rather than engage the Court by telephone.

(Paul Galea Deposition, Dec. 9, 2009 at 93:11-20, attached hereto as Exhibit A). Another example pertains to questioning on blend uniformity, an issue that Defendants have had with the blend for Digitek®.

> Q …Were you aware of blend uniformity problems among any product that was being produced at the Little Falls plant?
>
> MR. ANDERTON: Objection. I instruct the witness to answer only with respect to Digitek.
>
> THE WITNESS: I don't recall.

(Richard Dowling Depo., Dec. 16, 2009, 164:19-165:2, attached as Exhibit B). For additional examples see deposition excerpts attached hereto as Exhibit C.

a. Uniform Practices and Procedures in the Manufacturing Department

In PTO 27, Judge Stanley weighed Defendants' burden of producing documents requested by Plaintiffs against the potential benefit of such production. (*See* Order, ECF # 150, at p.15). For purposes of the instant motion, Defendants will suffer no burden or incur unusual expense in connection with answering deposition questions related to Actavis' quality unit and manufacturing processes for all drugs produced at the Totowa Little Falls Plant. As has been revealed during discovery and presented below, Defendants' argument that Digitek® is unique and essentially produced in a vacuum is untrue and the evidence evinced to support that position is ill-founded. In accord with Fed. R. Civ. P. 30, the testimony elicited is unquestionably relevant because it sheds light on the uniform practices and procedures inside the Actavis Totowa facilities pertaining to the manufacturing processes, quality control, and quality assurance, which ultimately lead to the termination of production of all products. In fact, the manager of the quality control lab testified that "the ceasing production was a decision made in general. Of course, including the digoxin." (Jisheng Zhu Depo., Jan. 27, 2010, 149:12-17,

attached hereto as Exhibit D). Yet Defense Counsel have consistently and repeatedly prevented witnesses from answering any questions concerning the cessation of production. (*See* examples in Exhibit C).

Naturally, the formulation and composition of a pharmaceutical product will be unique to its components when conceived; however, the evidence revealed in discovery has shown that manufacturing processes, equipment and personnel were interchangeable at the Little Falls plant. For example, Richard Dowling, former Director of Manufacturing Operations, stated that the processes were the same:

> Q. My understanding would be that while the blended ingredients are certainly different, the mechanism of pressing it into a tablet, the mechanism of blending, pressing and then moving it on out there, those would be essentially the same technologies, wouldn't it? …
> A. Yes.
> Q. …[I]f I went down a list of all the solid tablets at the Little Falls plant, the answer would be the same for those as well; isn't that right? …
> A. Yes.

(Richard Dowling Depo., 46:9-47:2). Further, he indicated that when he scheduled a production run, he picked operators based solely on their availability. (*See* Dowling Depo., 85:12-86:13).

b. Uniform Practices and Procedures in the Quality Department

The quality department is also critical to the proper functioning of a pharmaceutical plant. The quality department or unit for Actavis Totowa functioned out of the Little Falls Facility and the Riverview Facility. The quality unit includes quality assurance, quality control and quality systems. (Daniel Bitler Depo., Jan. 22, 2010, 213:13- 214:5, attached hereto as Exhibit E). The quality control laboratory conducts many of the in-process and finished product testing that is required by the FDA. Much like the manufacturing department, the processes, procedures and personnel are interchangeable and uniform for all of the drugs. Former Director of the Quality

Control Laboratory, Swapan Roychowdhury, verified that all high performance liquid chromatography chemists at Actavis would perform content uniformity tests on all products, and that specialized personnel were not assigned to test the content uniformity of specific drugs. (See Swapan Roychowdhury Depo., Dec. 15, 2009, at 192:19-195:4, attached as Exhibit F). Indeed, if Digitek® were to be tested for stability, friability, assay for blend, or assay the result would be the same – Digitek® would be tested by the same tester who was qualified to perform testing in the respective area just like the other 100 plus products made at Actavis. (*See id*. at 195:5-19).

When repeated documentation errors were observed by the FDA in the Actavis laboratory notebooks, the quality control analysts were retrained in documentation procedures for all products—not just those specific to Digitek®. (*See id*. at 240:7-241:8). Likewise, when Mr. Roychowdhury updated the chemists' out of specification investigation procedures, he instituted the modifications as to all products. (*See id*. at 251:8-252:12).

For a batch to make its way through the Actavis facilities into the market, the manufacturing department, quality department and packaging department must release the product. (Daniel Bitler Depo., at 28:17-29:10). If there is a finding that a tablet is out of specification in any of these departments then the quality unit will be involved in the investigation, if one is opened. There is not a separate unit to handle quality problems in manufacturing; it all falls under the quality department. (Scott Talbot Depo., Jan. 25, 2010, 45:9-13, attached hereto as Exhibit G). However, the departments work together and the relevant department, for example the manufacturing department, would assist the quality department in the investigation. (Daniel Bitler Depo., at 167:16-168:16). Notably, the FDA found significant issues with the quality unit at Actavis Totowa's Riverview facility.

> Q. During that period of time between 2007 and 2008, according to the FDA investigators, was there a total failure of the quality system?

A. According to the investigator, yes.

(Phyllis Lambridis Depo., Jan. 18, 2010, at 41:15-19, attached hereto as Exhibit H).

Many of the questions Defense Counsel have instructed the witnesses not to answer involve violations of the cGMPs and the findings of the FDA inspections.[2] Counsel's objections and instructions have prevented Plaintiffs from uncovering pertinent and relevant information. The cGMPs and any violation thereof apply across the board. For instance, Actavis' assistant QA manager, Paul Galea, stated that of the ten violations noted in the FDA's Feb. 1, 2007 revised warning letter, nine included GMP citations, which he concluded in his discussions with Actavis employees entailed looking at the general systems, not a particular drug. (Paul Galea Depo., at 89:7-90:16). Importantly, Mr. Galea, who was conducting a GMP assessment at the time, was never instructed or guided by management to evaluate GMPs as it pertains to particular products. (*Id.* at 19:15-20:4; 90:17-91:3). Tellingly, Mr. Galea testified as follows:

> Q. And, in fact, the GMP at Actavis Totowa, the procedures of GMP as used by the quality group pertained to all drugs, all products that were manufactured….
> A. Procedures are not product specific. Procedures tell you how to perform an operation.

(*Id.* at 91:4-14). Similarly, Actavis' Vice President of Regulatory and Medical Affairs, Ms. Terri-Lee Nataline testified that no differences exist between the standards applicable to Digitek® and those GMP standards applicable to the other drugs made by Actavis. (Terri-Lee Nataline Depo., December 14, 2009 at 45:5-9, attached hereto as Exhibit I).

[2] The issue of relevance of information concerning GMP violations was previously briefed by Plaintiffs in their prior Motion to Compel concerning the self-critical analysis privilege. (*See* Motion to Compel Documents and Deposition Testimony, unsealed version at ECF # 292, p. 15-16). Notably, this Court ruled that "[e]ven if the report prepared by Mr. Galea does not mention Digitek® or any other drug by name, as the Actavis Defendants represent, to the extent it deals with Actavis' Totoawa's GMPs around the time of the FDA's warning letters and ultimate recall of Digitek® such information is highly relevant, and in the absence of an applicable privilege or other reason to avoid production, must be turned over to Plaintiffs." (PTO # 52, ECF # 293, p. 12).

c. Broad nature of FDA inspections and observations concerning cGMP violations

To further illustrate the relevance of the Plaintiffs' questions, one must delve further into the FDA inspections. When the FDA does a complete GMP inspection of a plant, they look at six different systems in the plant. The inspector will start with the quality system because it is intertwined with all of the systems. The FDA does not investigate every single product implicated by a particular system. Rather, the FDA considers a representative sample of products to get a broad picture of the system. (Lambridis Depo., at 318:18-319:15). Although the 2007 inspection of the Little Falls facility included the Quality, Production, Laboratory Control, Materials and Facilities and Equipment Systems[3], the 2008 inspection of the Riverview facility included only the Quality System. Phyllis Lambridis, the former Vice President of Quality and Compliance at Actavis, Inc., explained the reach of the quality system.

> Q. So when [the FDA says] 'quality systems,' what different departments fall under that?
> A. Mainly QA, but it relates to other –it relates to all areas. That's why they look at the quality system because it relates to the entire facility. So it involves change control, annual product reviews, investigations, complaint handling, things that would go across the board.

(Lambridis Depo., at 325:22-326:7). Ms. Lambridis explained that the quality systems covered *all* drugs manufactured by the Totowa facilities. (Lambridis Depo., at 178:3-12). Interestingly, the 2008 FDA "inspection was limited to coverage of the Quality System due to significant cGMP deficiencies…" (Lambridis Depo., at 114:11-13). During the FDA inspection, the inspector spoke to Ms. Eyjofsdottir, the Global Vice President of Quality, and Ms. Lambridis, both of whom were upper level management and at highest echelons in the company for the quality system. During the inspection, they both "acknowledged the severity of the cGMP deficiencies and stated the need for corrective actions, restructuring of the Quality Unit, and

[3] The sixth system is packaging, which is located at the Taft Road facility.

hiring." (Lambridis Depo., at 120:3-17). Ms. Lambridis confirmed that these severe cGMP deficiencies would implicate the drug Digitek®. (Lambridis Depo., at 120:18-21).

It is clear that the serious and pervasive flaws in the quality system impact Digitek®. Ms. Lambridis explained that the FDA observations concerning the quality systems are general and they only give a few examples to substantiate a particular cGMP violation. An observation may mention only a few drugs as examples but if the problem is with a function of the system then the observations apply to all products manufactured at that particular facility. (Lambridis Depo., at 315:24-317:15; 334:18-337:10).

In any event, directing Actavis employees not to answer a question or answer only to the extent the response relates to Digitek®, based upon a PTO finding that production of documents would be too expensive, oppressive, and burdensome for Defendants skirts the very purpose of the federal discovery rules.[4] Moreover, Defendants' objections repeatedly fail to recognize the good cause standard referred to in PTO 27. (*See* PTO 27, ECF # 150, at 15). To be able to prove their case, Plaintiffs must be able to ask questions pertaining to relevant information. To prevent deponents from answering crucial questions which would require little additional time and no additional cost handicaps the Plaintiffs. To prohibit the reasonable and necessary inquiry into the quality and manufacturing departments of Actavis Totowa that pertains to all products including Digitek® would essentially rewrite the jurisprudence concerning discovery.

[4] The effect of Defendants' counsels' repeated instructions to deponents is far-reaching. In similar circumstances "a witness might be forced to evade or refuse to answer deposition questions. And those questions can be wide-ranging – Rule 26 of the Federal Rules of Civil Procedure requires only that 'the information sought appears reasonably calculated to lead to the discovery of admissible evidence.' Fed. R. Civ. P. 26(b)(1). The inevitable clashes between inquisitive deposing attorneys and recalcitrant witnesses will spawn discovery motions and appeals, all to be litigated in the courts. The resulting waste of individual and judicial resources would be far inferior to a system in which discovery proceeds unfettered, with witnesses confident that they cannot be punished for telling their tales." *Glover v. S.C. Law Enforcement Div.*, 170 F.3d 411, 415 (4th Cir. 1999) (declining to impose a reasonableness standard of protection upon a deponent's testimony in a Title VII action).

Defendants also mistakenly rely on PTO #12, the protective order, as justification to keep witnesses from answering questions. (Lambridis Depo., 295:1-3). The very nature of a protective order is to keep information from reaching the public, not to prevent the free flow of information between the parties during discovery. The provision allowing for redaction of some information applies only to "produced documents, materials or other things." It does not apply to witness testimony. (*See* PTO # 12, ECF # 71, p. 4, Section II(F)). Similarly, the section which specifically addresses the handling of confidential information during sworn testimony does not permit Defendants to instruct witnesses not to answer questions simply because Defendants believe the requested information is irrelevant. (*See id.* Section V).

II. Testimony Elicited is Relevant and Related to the Claims set out in the Master Complaint Because the Actavis Defendants Engaged in Uniform Practices and Procedures in their Manufacturing and Quality Departments with Digitek® and Other Drugs.

Defense Counsel's repeated instructions to witnesses not to answer questions preclude a reasonable inquiry clearly allowed under Rule 26 into areas encompassed by allegations in the Master Complaint. As noted by Judge Goodwin in PTO #37, the scope of discovery is determined by a party's complaint. (PTO # 37, ECF # 185, p. 5, 6). Rule 26 states that "parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party…" *See* Fed. R. Civ. P. 26(b)(1). Indeed, "[r]elevance for discovery purposes is defined more broadly that relevance for evidentiary purposes." *Kidwiler v. Progressive Paloverde Ins. Co.*, 192 F.R.D. 193, 199 (N.D.W.V. 2000) (internal citations omitted). Moreover,

> [i]nformation is relevant, for discovery purposes, if it 'bears on, or . . . reasonably could lead to other matter[s] that could bear on any issue that is or maybe in the case.' Although 'the pleadings are the starting point from which relevancy and discovery are determined . . . relevancy is not limited by the exact issues

> identified in the pleadings, the merits of the case, or the admissibility of discovered information.

Id. Accordingly, courts broadly construe relevancy in the context of discovery. *Id.*

> The 2000 amendments to Rule 26 created…two categories of discoverable information, one as a matter of right and one conditional on proof of good cause….The commentary rejects the bright line urged by the parties here, to allow only discovery as to the specific incident and specific product as a matter of right, with all other discovery requiring demonstration of good cause.
>
> Rather the commentary states:
>
> > A variety of types of information not directly pertinent to the incident in suit could be relevant to the claims or defenses raised in a given action. For example, other incidents of the same type, or involving the same product, could be properly discoverable under the revised standard.
>
> Accordingly, the commentary strongly indicates that "same" and, by extension similar incidents, products, etc. are related to the claim, not the subject matter; and therefore discovery is not dependent on demonstration of good cause.

United Oil Co., Inc. v. Parts Assocs., Inc. et al, 227 F.R.D. 404, 410 (D. Md. 2005) (internal citations omitted).

The Master Complaint specifically alleges violations of the regulations concerning the good manufacturing practices and gives examples of regulations that Defendants may have violated. (*See* Master Complaint, ECF # 73, ¶43; ¶94). The Master Complaint also clearly alleges adulteration and misbranding. (*See* Master Complaint ¶93).

The repeated violations of the cGMPs found at the Actavis Totowa facilities are relevant to the claims of the Plaintiffs.[5] The vast majority of violations cited by the FDA inspectors are system-wide and not limited to a specific product. These violations are clearly related to the cessation of production at the plant and a recall of every product made or tested at the Actavis

[5] In fact, such inquiry into cGMPs is crucial to Plaintiffs because drugs produced in violation of cGMPs contained in the Federal Regulations are deemed adulterated. (21 C.F.R. §210.1(b)).

Totowa facilities. A company would not recall all products unless there was a systemic problem that affected all products. To prevent the inquiry into the system-wide violations and resulting decisions made by management concerning those violations prevents the Plaintiffs from unearthing and fully grasping the true nature of problems that existed at the plant and which resulted in the Digitek® recall.

III. The Fallibility of Richard Dowling's Affidavit Calls into Question the Rationale Behind PTO #27.

Since the preparation of his affidavit, Plaintiffs have had the opportunity to depose Richard Dowling, the former Director of Manufacturing Operations for Actavis Totowa LLC at the Little Falls facility who provided an affidavit in support of Defendants' efforts to limit discovery to documents relating to Digitek®. His testimony revealed several inconsistencies suggesting that his affidavit is unreliable. In the affidavit, filed as Exhibit B to Defendant's Brief, Mr. Dowling stated:

> Digitek® is produced using what effectively is a custom, Digitek®-only tablet press. The base model and make of the tablet press used to manufacture all of the recalled Digitek® is a 45 station Stokes BB2 tablet press. Each time Digitek® is manufactured, the Stokes BB2 45 station press is customized using very unique "tooling" – punches and dies – **designed solely and used exclusively for the purpose of manufacturing Digitek® on that tablet press.**

(Richard Dowling Affidavit, June 22, 2009, ¶ 14, ECF # 146, p. 30-37) (emphasis added).

During Mr. Dowling's deposition, a December 18, 2007 e-mail from Mr. Dowling to Bharat Patel and Apurva Patel entitled "new punches Digoxin" exposed the following:

> As part of the corrective action for investigation number 07-093 for Digoxin double tablets, I am going to state that we buy a complete set of lowers and dies for both strengths of Digoxin that will be dedicated and not used for any other products. It is possible the tablet stuck to the punch and was double compressed.

> In addition, we should immediately do the same for the three strengths of – blank or redacted – right away.
>
> In the long run, the lower punches and dies will last longer if they are dedicated and not used for multiple products, and we won't have to delay set-ups because the lowers or dies needed are in use and not available

(Richard Dowling Depo., at 197:18-198:21). Upon questioning, Mr. Dowling admitted that the lower punches and dies at the Little Falls facility were not reserved solely for digoxin use.

> Q. Now, as of December 18, 2007, you did not have a set of lowers and dies that were dedicated solely to use to produce digoxin; isn't that right? …
> A. We had lower punches and dies as indicated in the production batch record available to use for digoxin….
> Q. Right. But the punches and dies were not reserved solely to use for digoxin were they?
> A. The lowers and dies were used interchangeably.
> Q. Okay. So when you say "interchangeably," you're saying that the lowers and dies were used for digoxin and for other products as well; isn't that right?
> A. Yes, they could be used for other products.
> Q. And what other products were they used for?
> A. That I don't recall. They would be products with the same die characteristic or size or the same punch or tablet configuration.

(Richard Dowling Depo., at 198:22-200:1). Magistrate Judge Stanley placed significant weight on Mr. Dowling's affidavit in rendering her ruling for PTO #27, even stating "[M]r. Dowling's affidavit states that the tools and dies used for tablet compression of Digitek® are utterly unique." (PTO #27 at 13, citing Dowling Aff. at ¶¶ 14-22.) Based upon Mr. Dowling's subsequent testimony, the information relied upon in issuing PTO #27 was fundamentally flawed and unreliable. Mr. Dowling has sworn a statement before this Court that is false and amounts to an inverse sham affidavit, in an effort to support Defendants' claims that Digitek®, Actavis' highest volume pharmaceutical product, is unique and effectively produced in a vacuum.

When probed if his attorney wrote the affidavit, Mr. Dowling responded, "Yes, my attorney assisted with this." (Richard Dowling Depo., at 210:7-20). Similarly, Mr. Dowling understood how his affidavit was going to be used.

> Q: You knew that by claiming that the process by which Digitek was produced was unique and used exclusively for the purpose of manufacturing Digitek, that that statement would be used to limit the scope of inquiry in this lawsuit; didn't you know that?
>
> A: I had an idea that may be what it was for, yes.

(Richard Dowling Depo. at 211:8-15.) Moreover, Mr. Dowling admitted he had no independent recollection of the 14 other products blended in the same room as Digitek® was blended (¶ 29 to his affidavit), nor the 10 other products that used the V-shaped blender that was used in the Digitek® blending process (¶ 30), nor the 6 other products pressed in either Room 119 or 120 other than Digitek® (¶ 34). (*See id.* at 213:3-8; 214:4-11; 216:24-217:6). Mr. Dowling procured this information by requesting the batch records from the document control area which took him the better part of two days to complete. (*Id.* at 213:9-19, 214:13-23). However, Mr. Dowling did not find this procedure unduly burdensome or oppressive and had immediate and inexpensive access to these documents. (*Id.* at 213:20-214:3; 215:2-15; 216:1-22). At the very least, Plaintiffs should be allowed to question deponents freely on the manufacturing processes and quality assurance procedures of all products produced during the relevant time period at the Little Falls facility.

IV. CONCLUSION

The deposition testimony sought is relevant, related to the claims of the Plaintiffs and reasonably calculated to lead to the discovery of admissible evidence because the Actavis Defendants engaged in uniform practices and procedures in their Manufacturing and Quality

Departments with Digitek® and other drugs. Further, Mr. Richard Dowling's Affidavit is unreliable and untrue nullifying the rationale of PTO #27.

Plaintiffs respectfully request that this Court grant this motion and enter an order compelling Defendants Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC to provide discovery including testimony relating to the above mentioned areas.

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Respectfully submitted,

On Behalf of the Plaintiffs' Steering Committee

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